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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/921,663 | 08/03/2001 | Philippe Pouletty | 500862000105 | 8307 |
| 20872 | 7590 | 05/04/2004 | EXAMINER | |
| MORRISON & FOERSTER LLP 425 MARKET STREET SAN FRANCISCO, CA 94105-2482 | | | GUPTA, ANISH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/921,663 | Applicant(s) POULETTY ET AL. | |
| | Examiner Anish Gupta | Art Unit 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 13-34 is/are pending in the application.
- 4a) Of the above claim(s) 13-22, 24, 25, 27-29 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 13, 23, 26, 30 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Applicant's election of X as the antiproliferative agent, Y is about 24 atoms linker, and Z is a maleimide group, dated 3/18/04, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants argued that they did not elect a sub-species of chemotherapeutic agents since a antiproliferative agent is a species of a generic "target entity." As explained to applicant in the interview, dated 2/19/04, that Applicants election will be accepted to further prosecution. However, the application will be examined to the point where a species reads on the generic election of X as the antiproliferative agent, Y is about 24 atoms linker, and Z is a maleimide group. The search will not be extended unnecessarily to cover all of the species covered by the election. If Applicants overcome the rejection in the next response, the prior art search will be extended to the extent necessary to determine patentability of the Markush-type election. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claims, reading on the species will be rejected and the action made final.

In the instant office action, prior art was found on the Markush type election. Claims 13, 23, 26, 30, 34 read on the prior art and have been rejected. Claims 13-22, 24-25, 27-29, 31-33 have been withdrawn from consideration.

Note that this application contained issues associated with 112 First paragraph. These claims have only been examined to the extent of 112 First paragraph issues and not prior art issues. Hence, even though they were included in the 112 rejection below, the claims are still held withdrawn from consideration as being drawn to being drawn to a non elected invention. These claims were included in the 112 First paragraph rejection to assist in furthering of prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 13-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states, “[a]n amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. In re Wright, 866 F.2d 422, 9USPQ2d 1649 (Fed. Cir. 1989).” Further, [w]hile there is no in *haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.”

Lack of ipsius verbis Support

In the instant case, the claims are drawn to “a therapeutic compound of the formula X-Y-Z.” First and foremost, the formula X-Y-Z does not appear any where in the specification. Indeed the variables X, Y or Z do not appear in any context, alone or in combination, in the specification. There is no *ipsius verbis* support for the formula X-Y-Z.

Lack of “implicit or inherent disclosure”

The MPEP states (“[W]here no explicit description of a generic invention is to be found in the specification[, ... mention of representative compounds may provide an implicit description upon which to base generic claim language.”); In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679, 683

Art Unit: 1654

(CCPA 1972). The specification, however, does not contain an specific examples that would lead one of ordinary skill in the art that X-Y-Z was implicitly disclosed in the compound. The specification does not exemplify any "antiproliferative" agents and only mentions the word "antiproliferative" in passing. For example, on page 16, antiproliferative agents, as a general proposition, are mention as "synthetic drugs" which may qualify as the second compound. However, the specification does not mention that these canbe incorporated in a any formula resembling X-Y-Z. There is, in fact, no support for the use of those agents to make anything resembling the compound X-Y-Z. Thus, it cannot be said that there is implicit, or inherent disclosure.

In their initial for amending the claim, dated September 26, 2000, it was indicated that generic composition support could be found on page 3, lines 15-19 and page 4, line 24. However, looking at these locations, there is mention of X-Y-Z or antiproliferative agent. The subsequent response stated that support for claim 34 could be found on page 5 and page 6. Again in reviewing these locations, the formula X-Y-Z is not disclosed, nor is the compound modified chemotherapeutic agent disclosed. The only thing disclosed is the linker. However, the linker, in itself, does not provide sufficient written description for X-Y-Z or other compounds that are modified such a antproliferative agent is linked to a maleimide group via a 24 atom linker.

Given the lack of support for the claimed amendment, the claims lack sufficient written description and constitute new matter in the Application.

Prior art Rejections

3. The instant application claims priority to a family of application which stem from 07592214 which was filed on 10/03/1990. The MPEP states "If the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as

Art Unit: 1654

lacking adequate written description, or in the case of a claim for priority under 35 U.S.C. 119, 120, or 365(c), the claim for priority must be denied." (MPEP 2163). For this reason, prior to the parent applications is denied.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 13, 23, 26, 30, 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Kratz et al. (WO 00/76550).

The claims are drawn to a modified chemotherapeutic agent of the formula X-Y-Z, where X is a chemotherapeutic agent, Y is a linker of 9 atoms in the chain, and Z is a maleimide group.

The reference discloses maleimide derivatives of doxorubicin (see page 26). The reference discloses a doxorubicin conjugated to a maleimide using the peptide QGAIFLPG. The doxorubicin is the antiproliferative drug X, since it is a cytotoxic agent for tumor cells. Z is a maleimide. Finally, the amino acid length leads to an exact 24 atoms in the peptide backbone, thereby meeting the limitation of Y. Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

Art Unit: 1654

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 23, 26, 30, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Someno et al.

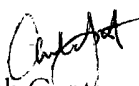
The claims are drawn to a modified chemotherapeutic agent of the formula X-Y-Z, where X is an antiproliferative agent, Y is a linker of 24 atoms in the chain, and Z is a maleimide group.

The reference teaches the compound peplomycin-polylysine-maleimide group (see abstract). The peplomycin is a chemotherapeutic agent that can qualify as an "antiproliferative drug" since it decreases the proliferation of tumor cells, thereby meeting the limitation of variable X. Z is maleimide. The X is the polylysine residues. The difference between the prior art and the instant application is that the reference does not teach the linker having specifically about 24 atoms. However, since the reference discloses the use of polylysine, which is (lysine)_n, it would have been obvious to optimize the amount of lysine residues to get the desired length. Note that the attached registry print out indicates that the lysine residues, in the polylysine, are variable.

Art Unit: 1654

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta
Patent Examiner
April 29, 2004